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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,913	01/10/2006	Konsei Shino	900-539	5635

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EXAMINER

CUMBERLEDGE, JERRY L

ART UNIT	PAPER NUMBER
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3733

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/563,913

Applicant(s)

SHINO, KONSEI

Examiner

Jerry Cumberledge

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 January 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>10/04/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3 and 8-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Hoffman et al. (US Pat. 5,021,056).

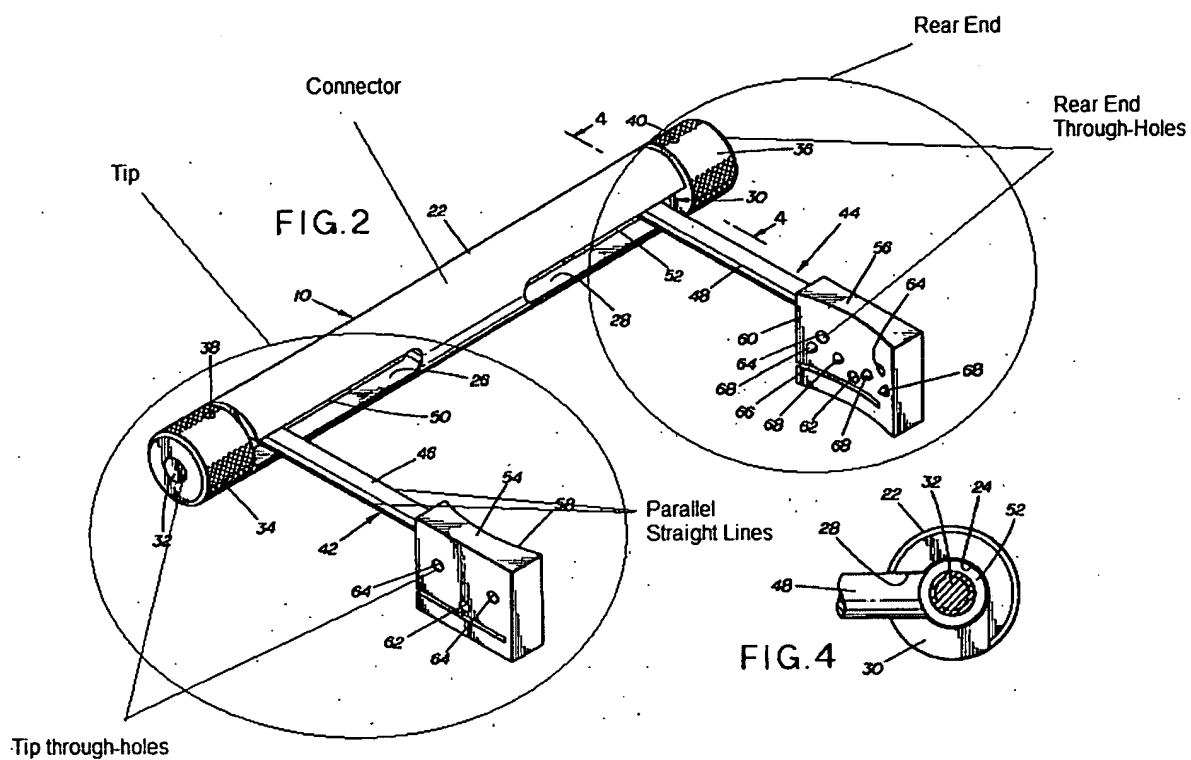
Hoffman et al. disclose a device for ligament reconstruction comprising: a tip (Fig. 2 below) having two parallel through-holes (Fig. 2 below) formed therein in juxtaposition; a rear end having two through-holes (Fig. 2 below and Fig. 3 below) formed therein in juxtaposition coaxially with the two through-holes of the tip portion; and a connector (Fig. 2 below) connecting the rear end and the tip and having a single connection hole (Fig. 3 below) connecting one of the through-holes of the tip portion coaxially to one of the through-holes of the rear end portion, the connector being thinner and longer than the tip and the rear end (Fig. 3), wherein the tip has a generally elliptical (Fig. 2, the portion of rod 46) or rectangular cross section (rectangular, Fig. 2, ref. 54) elongated in a direction in which the through-holes thereof are juxtaposed, so that the

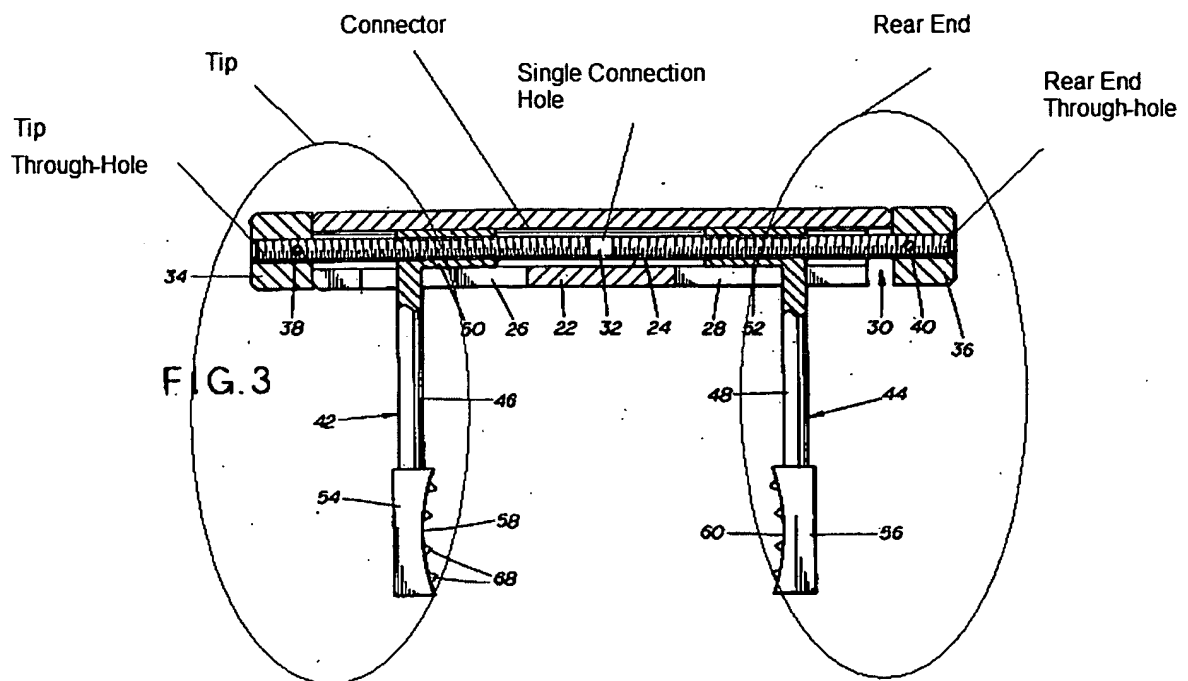
Art Unit: 3733

tip is capable of being driven into an articular bone to form a flat socket in the bone by hitting the rear end portion.

The elliptical cross section is of a generally oval shape or a racetrack-like elliptical shape. The cross section of rod 46 is a circle, and circles are ellipses. The racetrack-like elliptical shape is defined by a pair of parallel straight lines (Fig. 2 below) and a pair of semicircles connecting opposite ends of the straight lines. The semicircles are the two curved surfaces that extend around the rod 46 and connect the parallel straight lines. The connection portion has a generally round or oval cross section (Fig. 2, ref. 22). The device is capable of performing reconstruction of an anterior cruciate ligament graft. The cross-section is generally perpendicular to a longitudinal extending direction of the through holes of the tip (Fig. 4, below).

Hoffman et al. further disclose drills (column 5, lines 16-18) and guide pins (column 3, lines 33-34).





With regard to statements of intended use and other functional statements (e.g. "...for ligament reconstruction...", "...reconstruction of an anterior cruciate ligament graft..."), they do not impose any structural limitations on the claims distinguishable over the device of Hoffman et al., which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be

Art Unit: 3733

employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

The device of Hoffman et al. is capable of performing a method for ligament reconstruction utilizing a ligament reconstruction device as recited in claim 1, the method comprising the steps of: drilling a guide pin into an articular bone; fitting the guide pin in two of the through-holes and the connection hole of the ligament reconstruction device aligned with each other, and drilling another guide pin into the articular bone through the other two through-holes of the ligament reconstruction device; removing portions of the bone around the previously-inserted two guide pins by over-drilling; and driving the tip portion of the ligament reconstruction device into the articular bone toward a lateral cortex of the articular bone by hitting the rear end portion of the ligament reconstruction device with the two guide pins respectively fitted in the two through-holes and the connection hole of the ligament reconstruction device aligned with each other and in the other two through-holes of the ligament reconstruction device to form a flat socket into which one end portion of a ligament graft is to be inserted. The flat socket has a depth of 10 to 23 mm. The ligament graft is an anterior cruciate ligament graft with a bone piece. The ligament reconstruction is reconstruction of an anterior cruciate ligament graft, and the articular bone is a femur.

Claims 15 and 17 are rejected under 35 U.S.C. 102(e) as being anticipated by Huebner et al. (US Pub. 2004/0102788 A1).

Huebner et al. disclose a device for ligament reconstruction comprising a tip (Fig. 3, ref. 94) having either one of a generally rectangular or elliptical cross-section (Fig. 3, ref. 94), wherein said tip has generally parallel first (Fig. 3, ref 59, left) and second tip through-holes (Fig. 3, ref. 59, right) formed in juxtaposition inside of said rectangular or elliptical cross-section; a rear-end (Fig. 3, ref. 76) having generally parallel first (Fig. 3, ref. 92, left) and second rear-end through-holes (Fig. 3, ref. 92, right) formed therein in juxtaposition, and wherein said first and second rear-end through holes extend coaxial with said first and second tip through holes (Fig. 2), respectively; and a connector (Fig. 3, ref. 60) which connects said rear-end and said tip, wherein said connector has a connection hole (Fig. 3, bore through ref. 60) which connects one of said first and second tip through-holes coaxially with one of said first and second rear-end through-holes (Fig. 2), wherein said connector is thinner and longer than both said tip and said rear-end (Fig. 3). With regards to the cross-section of the tip, the tip is angled relative to the rest of plate (as seen in Fig. 2, near ref. 59), therefore a planar cross-section taken across this angled portion (i.e. the tip) would yield a generally elliptical cross-section, since the cross section would exclude the other elongated portions of the plate (as best labeled and shown in Fig. 6, ref. 132). With regards to the connector connecting the front and rear holes, since the connector is adjustable (Fig. 5, arrow), the connector can be adjusted so that it is placed against the tip portion, hence it would connect the rear-end through hole to the front hole. The race-track like elliptical shape is defined by a pair of parallel straight lines (Fig. 4, near where the ref. 92 numbers are written) and a

pair of semicircles connecting opposite ends of the straight lines (Fig. 4, the semicircles on the left and right ends of the ellipse).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2 and 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoffmann et al. (US Pat. 5,021,056).

Hoffman et al discloses the claimed invention except for the generally elliptical or rectangular cross section having a major axis/minor axis ratio of 2 to 5; the racetrack-like elliptical shape being defined by a pair of parallel straight lines spaced a distance of 3 to 6mm from each other and each having a length of 4 to 8mm; the rectangular cross section having a minor edge length of 3 to 6mm and a major edge length of 7 to 14mm; the tip portion having a cross sectional area of 21 to 84 mm²; the tip portion having a length of 5 to 10mm.

With regard to claims 2, 4, 5, 6 and 7, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device for ligament reconstruction of Hoffman et al. with the generally elliptical or rectangular cross section having a major axis/minor axis ratio of 2 to 5; the racetrack-like elliptical shape being defined by a pair of parallel straight lines spaced a distance of 3 to 6mm from

Art Unit: 3733

each other and each having a length of 4 to 8mm; the rectangular cross section having a minor edge length of 3 to 6mm and a major edge length of 7 to 14mm; the tip portion having a cross sectional area of 21 to 84 mm²; the tip portion having a length of 5 to 10mm. It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claims 16 and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huebner et al. (US Pub 2004/0102788 A1).

Huebner et al. discloses the claimed invention except for the generally elliptical or rectangular cross section has a major axis/minor axis ratio of about 2 to about 5; the pair of parallel straight lines spaced a distance of about 3mm to about 6mm from each other and each having a length of about 4mm to about 8mm; the rectangular cross section has a minor edge length of about 3mm to about 6mm and a major edge length of about 7mm to about 14mm; and the tip has a cross sectional area of about 21mm² to about 84mm².

With regards to claims 16 and 18-20, it would have been obvious to one having ordinary skill in the art at the time the invention was to have constructed the device of Huebner et al. with the generally elliptical or rectangular cross section of having a major axis/minor axis ratio of about 2 to about 5; the pair of parallel straight lines being spaced a distance of about 3mm to about 6mm from each other and each having a length of about 4mm to about 8mm; the rectangular cross section having a minor edge length of

Art Unit: 3733

about 3mm to about 6mm and a major edge length of about 7mm to about 14mm; and the tip having a cross sectional area of about 21mm² to about 84mm², since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Response to Arguments

Applicant's arguments filed 01/03/2007 regarding claims 1-13 have been fully considered but they are not persuasive.

With regards to Applicant's argument that the Hoffman reference does not disclose a tip having a generally elliptical or rectangular cross-section, the Examiner respectfully disagrees. A cross section taken along the end of the device near ref. 32 of Fig. 4 would yield a generally elliptical (in this case circular, and since all circles are ellipses, elliptical) cross-section.

Applicant's arguments with regard to claims 2, 4, 5, 6 and 7 do not overcome the rejections applied thereto, since applicant has not provided any convincing showing that these are nothing more than optimum or workable values as asserted by the examiner. Applicant has not provided any showing that such limitations are "critical". In re Cole, 140 USPQ 230 (CCPA 1964); In re Kuhle, 188 USPQ 7 (CCPA 1975); In re Davies, 177 USPQ 381 (CCPA 1973). Mere arguments by counsel cannot take the place of evidence. In re Cole, 236 F.2d 769, 773, 140 USPQ 230, 233 (CCPA 1964); In re Walters, 168 f.2d 79, 80, 77 USPQ 609, 610 (CCPA 1948); et al. Furthermore, applicant

Art Unit: 3733

states that the ranges disclosed are preferable (e.g. Page 5, lines 6-7, Page 5, line 16), which indicates that the ranges are not critical, but rather are preferred.

With regards to the double patenting rejection, the full double patenting rejection can be found in the Office Action regarding application No. 10563915. The information regarding the double patenting rejection was placed in the current Office Action to inform the Applicant that there exists (or existed previously, if the rejection has been withdrawn from the copending application) a double patenting rejection between this application and copending application No. 10563915.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Art Unit: 3733

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Cumberledge whose telephone number is (571) 272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JLC



EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER